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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 558

Display Date 9-1-05
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Certifier *[Signature]*

New Animal Drugs; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for an approved new animal drug application (NADA) from Alpharma Inc., to Pharmaq AS. The drug labeler code for Pharmaq AS is also being listed.

DATES: This rule is effective *[insert date of publication in the Federal Register]*.

FOR FURTHER INFORMATION CONTACT: David R. Newkirk, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6967, e-mail: *david.newkirk@fda.gov*.

SUPPLEMENTARY INFORMATION: Alpharma Inc., One Executive Drive, Fort Lee, NJ 07024, has informed FDA that it has transferred ownership of, and all rights and interest in, NADA 125-933 for ROMET-30 (sulfadimethoxine/ormetoprim) Type A medicated article to Pharmaq AS, Skogmo Industriomrade, N-7863 Overhalla, Norway. Accordingly, the agency is amending the regulations in 21 CFR 558.575 to reflect the transfer of ownership.

In addition, Pharmaq AS has not been previously listed in the animal drug regulations as a sponsor of an approved application. Accordingly, 21 CFR 510.600(c) is being amended to add entries for Pharmaq AS.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 558

Animal drugs, Animal feeds.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510 and 558 are amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

■ 2. Section 510.600 is amended in the table in paragraph (c)(1) by alphabetically adding a new entry for “Pharmaq AS” and in the table in paragraph (c)(2) by numerically adding a new entry for “015331” to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
Pharmaq AS, Skogmo Industriomrade, N-7863 Overhalla, Norway	015331

(2) * * *

Drug labeler code	Firm name and address
015331	Pharmaq AS, Skogmo Industriomrade, N-7863 Overhalla, Norway

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

- 3. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

§ 558.575 [Amended]

■ 4. Section 558.575 is amended in paragraph (a)(2) by removing "046573" and by adding in its place "No. 015331".

Dated: August 22, 2005
August 22, 2005.

Steven D. Vaughn dm

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